

Check out the SPL Working Group WIKI @:  
<http://spl-work-group.wikispaces.com>

**Questions on SPL:**

ER/DL regulatory questions? Send to [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

SPL technical questions? Send to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)

UNII or SRS questions? Send to [fda-srs@fda.hhs.gov](mailto:fda-srs@fda.hhs.gov)

*As of May 5, 2011: DailyMed has over 23,300 SPL loaded.*

**Minutes:**

**Overview of ER/DL meeting with CMS**

CMS is responsible for administering the Medicare Part D statute related to drug reimbursement. The statute contains a definition of drugs for reimbursement which meet the measures of safety and efficacy, and are within certain therapeutic categories. Still, it is not always easy to know which products/NDCs are reimbursable because categories aren't obvious.

CMS would like to use the FDA's NDC Directory as the 'gold standard' for a drug being properly listed and having been approved by FDA in the US using measures of safety and efficacy. Thus, products on the NDC Directory can be considered actively marketed and eligible for reimbursement.

Challenges:

- Determining therapeutic category of a drug product/NDC
- Knowing if an drug product/NDC is still actively marketed
- Non-agreement between the NLM's RxNorm database and NDC Directory
- Discrepancies between NDC Directory, Orange Book and other sources
- Lack of certain needed information in NDC Directory, eg, if product is brand or generic
- Format of NDCs is 10 digits instead of widely used HIPAA 11-digit format
- Manufacturers don't always drug list inner package NDCs
- Many data sources with limited flexibility for searching and cross-matching information

Drug Listers: Use the last lot expired for the Market End Date for delisting purposes

**Medicare Coverage Gap Discount Program Manufacturer Agreement**

<https://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/ManuAgreement.pdf>

## **Question about letters from DRLS to sponsors regarding inaccurate or incomplete drug listing information**

Form letters with Listing at end of letter indicating that there may be errors in the listing. How are people handling these? Several respondents have responded to the FDA. Several have found that the letter was in error, and pointed out why this was so.

Address mismatches (API Manufacturers have the wrong address compared to D&B)?

Registration of a campus (rather than each) – used the DUNS that had worked for several years. It now causes validation errors. How did you list the address? There are 5 or 6 addresses all on the same street. One FEI number, multiple addresses. Try semi colons.

## **Lot distribution data in SPL**

This is in the SPL standard. FDA is interested in using this as a new data element in the future. The Technical Team will be discussing this further at an upcoming meeting.

## **Pharm Class - biologics**

CBER is working on some established pharmacologic class terminology for Biologics. They hope to provide more information in a couple months.

Any feedback from those who have used DailyMed new query feature?  
Can be a nifty feature. Not a lot of experience with this yet.

DailyMed web page - question regarding inconsistency of statements: grey box at top of page states it contains the current in use - text under "About DailyMed" states labeling may not be the currently distributed

Action: send this possible correction to DailyMed.

## **Use of "Nursing Mothers" vs "Nursing Women"**

At least one participant has been asked by FDA to change the section heading for 8.3 Nursing Mothers to 8.3 Nursing Women. How to address? Others encouraged checking back with the FDA and referencing PLR regulatory documentation.

## **Guidance on pharmacogenomics (12.5)**

Draft Guidance (Feb 2011) gives an example where pharmacogenomics was assigned 12.5.

"...The detailed information will most often appear in the Pharmacogenomics subsection of CLINICAL PHARMACOLOGY (12.5) or CLINICAL STUDIES section (14)."

[Clinical Pharmacogenomics: Premarketing Evaluation in Early Phase Clinical Studies \(PDF -](#)

[531KB\)](#)

**Side comment – 12.4 reserved for Microbiology**

Link to guidance (page 9 has Microbiology Section reference):

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm109739.pdf>

**FDA On-Line Repository**

Check it out here: <http://labels.fda.gov>

Searchable by:

[Proprietary Name Search](#) [NDC Number Search](#)

[Active Ingredient Search](#) [Application Number or Regulatory Citation Search](#)

[Company Search](#)

Next meeting scheduled for:

**Wednesday, May 18, 2011**

**Time: 1:00-2:30 ET**

**Dial-in info: number 1-877-423-2663 PIN# 240184**

- Minutes of previous Process Team meetings are here:  
<http://spl-work-group.wikispaces.com/Process+Communications+Forum>